

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,506	04/22/2004	Marvin John Cervantes	P1482 US (2650/81)	7331
	7590 02/05/200 VASCULAR, INC.	EXAMINER		
3576 Unocal Place			RYCKMAN, MELISSA K	
Santa, Rosa, CA 95403			ART UNIT	PAPER NUMBER
			3773	
•			MAIL DATE	DELIVERY MODE
			02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

, ,		Application No.	Applicant(s)
		10/829,506	CERVANTES, MARVIN JOHN
Office Action Summary		Examiner	Art Unit
	·	Melissa Ryckman	3773
	The MAILING DATE of this communication app		
Period fo			
WHIC - Exte after - If NC - Failt Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATES OF THE MAILING DA	ATE OF THIS COMMUNIC 36(a). In no event, however, may a re will apply and will expire SIX (6) MON , cause the application to become AB	CATION. eply be timely filed THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).
Status			
1)⊠ 2a)⊠ 3)⊟	Responsive to communication(s) filed on <u>01 O</u> This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matte	
.	·	en parto quayro, 1000 C.D	. 11, 100 0.0. 2.0.
•	ion of Claims		
5)□ 6)⊠	Claim(s) 1-12 and 16-21 is/are pending in the 4a) Of the above claim(s) 2-4,10-12,16-21 is/are Claim(s) is/are allowed. Claim(s) 1 and 5-9 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/o	e withdrawn from conside	ration.
Applicat	ion Papers		
9)[The specification is objected to by the Examine	or.	
10)	The drawing(s) filed on is/are: a) acc	epted or b)⊡ objected to i	by the Examiner.
	Applicant may not request that any objection to the		
11)□	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	•	
Priority (under 35 U.S.C. § 119		
12)[a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureau See the attached detailed Office action for a list	s have been received. s have been received in A rity documents have been u (PCT Rule 17.2(a)).	pplication No received in this National Stage
Attachmen		_	
2) Notic 3) Infor	ee of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	Paper No(s	oummary (PTO-413) s)/Mail Date nformal Patent Application

Art Unit: 3773

DETAILED ACTION

This office action is in response to claims and arguments submitted 10/1/07.

Election/Restrictions

Claims 11,12,16-19 are directed towards species D, therefore they have been withdrawn, in addition to claims 2-4,10,20 and 21 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species B, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/1/07.

Drawings

The drawings are objected to because there is no line B-B in Fig. 6 as stated in page 11 line 28 of the specification, Figs. 6-8 show the port as 610,710, and 810 respectively, however the claims state that the port includes a lock. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the o-ring must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

Application/Control Number: 10/829,506 Page 3

Art Unit: 3773

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,5-9 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification and the drawings fail to show an o-ring having an o-ring diameter wherein a proximal portion of the sleeve is **positioned proximal** to the port vessel. The previous set of claims did not include language for the positioning of the sleeve with respect to the o-ring.

Claim Rejections - 35 USC § 102

Application/Control Number: 10/829,506

Art Unit: 3773

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5,7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (U.S. Patent No. 6,270,521).

Claim 1:

Fischell teaches a system for treating a vascular condition, comprising: a catheter (12); a stent assembly (40) coupled to the catheter; the stent assembly comprising a coated stent including a stent framework and a drug coating disposed on at least a portion of the stent framework (col. 5, II. 32-34); a protective sleeve (34) removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter (fig. 2b); and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly (fig. 2b), and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open (fig. 2b), wherein the protective sleeve is removed from covering the stent (fig. 2c) framework prior to deploying the stent, and a port to a vessel (18), the port including an o-ring having an o-ring inner diameter (portion of 18 acts as an o-ring), wherein a proximal portion of the sleeve (34) is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter (Fig. 2c).

Art Unit: 3773

Claim 5:

Fischell teaches the sleeve comprises a material selected from the group consisting of nylon, polyurethane, polyethylene terephthalate, polyethylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, an elastane, a thermoplastic elastomer, a woven polymeric fabric, or an expandable polymeric sheet (nylon, col. 2, II. 50-52).

Claims 7 and 8:

Fischell teaches a lubricious coating on at least a portion of a surface of the sleeve (col. 2, Il. 54), the examiner interprets the coating to be a lubricious film.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Patent No. 6,270,521) as applied to claim 1 above.

Claim 6:

Fischell teaches the invention as claimed above, however does not specify the sleeve comprising a material that dissolves while in a vasculature. It would have been obvious to one of ordinary skill in the art to use a biodegradable material as it is well

Art Unit: 3773

known in the art to use a biodegradable material for a stent sleeve, as this omits a surgery to remove the sleeve later on.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Patent No. 6,270,521) as applied to claim 1 above, and further in view of Roberts et al. (U.S. Patent No. 5,984,964).

Fischell teaches the claimed invention above, however does not specify dimensions of the sleeve, however Roberts teaches the sleeve has a distal inner diameter of substantially .071 centimeters, a distal outer diameter of substantially .0825 centimeters (col. 4, II. 52-59), a medial inner diameter (L7) of .045 centimeters, and a medial outer diameter of .055 centimeters (col. 4, II. 59-63).

It would have been obvious to one of ordinary skill in the art to have the dimensions of Roberts as these dimensions are appropriate for use in the vasculature.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Application/Control Number: 10/829,506

Art Unit: 3773

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Application/Control Number: 10/829,506

Art Unit: 3773

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Page 8

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/Darwin P. Erezo/ Primary Examiner, Art Unit 3773